REMARKS

Claims 62-99 were pending in the present application. Claims 64-67 and 78-81 were previously withdrawn from consideration as being drawn to non-elected species. Accordingly, claims 62-63, 68-77, and 82-99 are currently under examination.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

As of the Office Action of July 26, 2001, the following issues were still outstanding:

(a) submission of additional copies of references 23-102 in the Information Disclosure Statement which was submitted on April 15, 1999;

(b) rejection of claims 75, 89, and 99 under § 112, second paragraph;

(c) rejection of claims 75, 89, and 99 under § 112, first paragraph;

(d) priority claim of claims 62-99 to 08/372,676, now U.S. Patent 5,612,030;

(e) rejection of claims 62-63, 68-77, and 82-99 under § 103(a) as allegedly unpatentable over Chatterjee et al., U.S. Patent 5,612,030, and further in view of Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988);

(f) rejection of claims 76-77, 89-89, and 90-99 under § 103(a) as allegedly unpatentable over Chatterjee et al., *J. Immunol.* 150 (vol. 8, part 2) 142A, Abstract 805, 1993) and further in view of Saleh et al. (*J. Immunol.* 151:3390-3398, 1993) and Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988);

(g) rejection of claims 76-77, 82-99 and 90-99 under § 103(a) as allegedly unpatentable over Chatterjee et al. (*J. Immunol.* 150 (vol. 8, part 2) 142A Abstract 805, 1993) and further in view of Cheung et al.(*Int. J. Cancer* 54:499-505, 1993) and Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99, 1988).

Information Disclosure Statement

In the Office Action of July 26, 2001 (Paper No. 13), the Examiner acknowledged Applicants' previous statement that they would supply copies under separate cover of references 23-102 in the Information Disclosure Statement submitted on April 15, 1999. This statement was made in response to a request for copies of these references by the Examiner in the Office Action of November 29, 2000 (Paper No. 10). In accordance with this request, Applicants submitted references 23-94 and 96-102 on July 18, 2001. Reference 95 was unavailable at that time.

Applicants are submitting reference 95 with this response. The Examiner should now have a complete set of copies of references 23-102. Applicants would appreciate the Examiner considering all of the references and initialing them on the Form PTO-1449.

Withdrawal of previous rejections and objections

Applicants acknowledge with appreciation the withdrawal of the rejection of claims 62, 63, and 68-74 under 35 U.S.C. § 112, first paragraph.

Applicants would appreciate the Office officially withdrawing the previous objections to the drawings and the specification, to the extent that they were not reiterated in the Office Action of July 26, 2001 (Paper No. 13).

Rejections under 35 U.S.C. §112, second paragraph

Claims 75, 89, and 99 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting the phrase "heat-treating an antibody." Applicants respectfully traverse this rejection.

The Examiner states that Applicants' previous argument, that the meaning of "heat-treated" would be evident to one of skill in the art, is unpersuasive. In response, Applicants reiterate their previous argument that the meaning of the phrase "said antibody is heat-treated prior to administration" would be evident to one of skill in the art. In response to the Examiner's

statement that it is not clear what temperature is intended, Applicants maintain that a skilled artisan would understand the meaning of this phrase and would be able to readily determine appropriate temperatures for heating within the context of the functional embodiments of claims 75, 89, and 99, which are directed to heat treating an antibody prior to its administration to an individual for delaying recurrence or delaying development of a GD2-associated tumor, or treating an individual with a GD2-associated tumor. For example, the specification teaches that a vaccine composition comprising 1A7 antibody may be incubated to about 48°C for about 30 minutes (page 54, lines 15-16). Other appropriate temperatures, that allow the antibody to retain its "effective" properties, as recited in the claims, would be readily apparent to one of skill in the art.

The Examiner states that heat treatment of an antibody does not seem to be recognized in the art because a search of the patent database did not indicate any patents with these terms. However, Applicants respectfully note that when the USPTO database was searched, entering the terms "heat-treated" and "antibody," two issued patents containing these terms in the claims were found, U.S. patent numbers 6,235,280 and 6,274,143. As in the present application, both of these patents claim heat treating an antibody prior to administration to an individual, for treatment of a disease condition. Therefore, contrary to the Examiner's assertion, heat treatment appears to be an art recognized term, particularly in light of the fact that claims containing this term and directed to methods similar to those of the present application have already been issued by the Office.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. §112, first paragraph

Claims 75, 89, and 99 are rejected under 35 U.S.C. §112, first paragraph. The Examiner states that the claims encompass any temperature and that while a temperature that causes denaturation of the antibody would not be an "appropriate heating temperature," the claims

encompass any temperature and time, while the specification only enables heating to about 48°C for about 30 minutes. The Examiner states that it would require undue experimentation for one of skill in the art to practice the claimed invention.

Applicants respectfully traverse and maintain that one of skill in the art would be able to practice the claimed invention without undue experimentation. Guidance in the specification is provided in the form of an example of appropriate heating conditions, about 48°C for about 30 minutes (page 54, lines 15-16). Further, as the Examiner has admitted, a temperature that causes denaturation of the antibody would *not* be an appropriate heating temperature. It would be a matter of routine for a skilled artisan to determine an appropriate heating temperature at which the antibody is structurally and functionally intact. Determining an appropriate temperature in the range between ambient temperature and the temperature at which the antibody is denatured would be well within the routine abilities of one of skill in the art and would not require undue experimentation.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under U.S.C. § 112, first paragraph.

Priority

The Examiner has reiterated the assertion that claims 62-89 should be granted the priority date of application 08/591,196, now U.S. Patent 5,977,316, instead of the priority date of application 08/372,676, now U.S. Patent 5,612,030. Although the Examiner admits that "it may by true that it is inherent that the 1A7 antibody contains the sequence of SEQ ID Nos 2 and 4," he alleges that "the limitations of any antibody comprising the light and heavy chain variable region sequences in SEQ ID Nos 2 and 4 are not seen in the 08/372,676 application" (Paper No. 13, page 4). Applicants respectfully traverse.

As an initial matter, Applicants note that claims 64-67 and 78-81 have been withdrawn from consideration as being directed to a non-elected species. Further, claims 90-99 were added in the response to Paper No. 10, filed on May 29, 2001, and since these claims recite "an

antibody comprising the light and heavy chain variable region sequences contained in SEQ ID NO:2 and SEQ ID NO:4, respectively," the priority date issue appears to encompass these claims as well. Applicants therefore assume that the priority issue applies to currently-pending claims 62-63, 78-77, and 82-99.

In response to the Examiner's statement that SEQ ID Nos 2 and 4 are not "seen" in the 08/372,676 specification, Applicants respectfully note that "[t]he subject matter of [a] claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement" (MPEP § 2163.02). This requirement is met if "the disclosure of the [earlier] application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter" (*Lampi Corp. v. American Power Products*, 228 F. 3d 1365, 1378 (Fed. Cir. 2000), citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)). With respect to the present application, although an antibody comprising the light and heavy chain variable region sequences in SEQ ID Nos 2 and 4 was not described *in haec verba* in the specification of 08/372,676, it would be clear to an artisan that Applicants had possession of this subject matter, because the application disclosed antibody 1A7 and the hybridoma that produces this antibody. The amino acid sequences of the polypeptides contained in the 1A7 antibody, and fragments thereof, are inherent in the structure of the antibody.

Applicants submit that the standard for a claim of priority to a prior application is not whether particular claim limitations are "seen" in the parent application, as asserted by the Examiner, but rather whether they inherently flow from the earlier disclosure. This standard is set forth in *Kennecott Corp. v. Kyocera International, Inc.*, 835 F.2d 1419 (Fed. Cir. 1987). In *Kennecott*, patent claims to a sintered ceramic body containing the words "equiaxed microstructure" were granted the priority date of a parent application that did not recite these words. The only additional disclosure that was not in the earlier-filed application was a description and pictures of the product's microstructure. The court held that the claims were entitled to the earlier priority date because the additional disclosure was merely of the existing

physical structure of the product, rather than of a new use for the product (*Id.* at 1423). Similarly, in the present application, the sequences contained in SEQ ID Nos 2 and 4 are part of the existing physical structure of the 1A7 antibody, which was disclosed in 08/372,676. The Examiner has admitted that SEQ ID Nos 2 and 4 are inherently contained in the 1A7 antibody (Office Action, page 4). Applicants maintain that an antibody containing the variable region sequences contained in SEQ ID Nos 2 and 4 inherently flows from the disclosure of the 1A7 antibodies in 08/372,676 and that the pending claims of the present application are therefore entitled to the benefit of the priority date of January 17, 1995.

In view of the foregoing, Applicants respectfully request that the pending claims be afforded the priority date of application 08/372,676, now U.S. Patent 5,612,030.

Rejections under 35 U.S.C. § 103(a)

A. Claims 76-77 and 82-99 stand rejected as allegedly unpatentable over Chatterjee et al. (U.S. Patent No. 5,612,030) and further in view of Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99 (1988)). Applicants respectfully traverse this rejection in that the claims are entitled to the priority benefit of the filing date of the patent application corresponding to the Chatterjee patent. Thus, the Chatterjee patent should not be cited as a reference.

Applicants note that a Continuing Prosecution Application (CPA) has been filed. At the time this invention was made, the subject matter of U.S. Patent No. 5,162,030 and Applicants' claimed invention were subject to an obligation of assignment to the same entity. Therefore, under 35 U.S.C. § 103(c), which applies to any application for patent filed on or after November 29, 1999, U.S. Patent No. 5,162,030 does not qualify as a reference to preclude patentability under §103(a).

B. Claims 76-77 and 82-99 stand rejected as allegedly unpatentable over Chatterjee et al. (*J. Immunol.* 150 (8, part 2), 142A, Abstract 805 (1993)), further in view of Saleh et al. (*J. Immunol.* 151: 3390-3398 (1993)) and Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99 (1988)).

The Examiner states that submission of copies of declarations submitted by S. Chatterjee and M. Chatterjee in application 08/372,676 would be sufficient to obviate this rejection. Copies of these declarations are attached to this Amendment.

The Examiner also states that Applicants argued in their response of May 29, 2001 that evidence obtained in a rabbit model would not correlate with results expected in humans. In response, the Examiner states that the claims recite an "individual," which would encompass a rabbit because this term is defined in the specification as "a vertebrate, preferably a mammal." Applicants respectfully submit that the Examiner misinterpreted Applicants' previous statement. Applicants pointed out that Ab3 production in healthy rabbits with *no disease* in response to administration of *a different anti-idiotype antibody* (as disclosed in Saleh et al.) does not sufficiently relate to administration of 1A7 antibody to *diseased* individuals, and that Saleh et al. should therefore not serve as a basis for obviousness (see page 13 of the response filed on May 29, 2001). However, this point is moot in view of removal of the Chatterjee patent as a reference.

C. Claims 76-77 and 82-99 stand rejected as allegedly unpatentable over Chatterjee et al. (*J. Immunol.* 150 (8, part 2) 142A, Abstract 805 (1993)), further in view of Cheung et al. (*Int. J. Cancer* 54: 499-505 (1993)) and Harlow et al. (Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, pages 96-99 (1988)).

The Examiner states that submission of copies of declarations submitted by S. Chatterjee and M. Chatterjee in application 08/372,676 would be sufficient to obviate this rejection. Copies of these declarations are attached to this Amendment.

The Examiner also states that Applicants argued in their response of May 29, 2001 that evidence obtained in a mouse model would not correlate with results expected in humans. In response, the Examiner states that the claims recite an "individual," which would encompass a mouse because this term is defined in the specification as "a vertebrate, preferably a mammal." Applicants respectfully submit that the Examiner misinterpreted Applicants' previous statement. Applicants pointed out that Ab3 production in healthy mice with *no disease* in response to administration of *a different anti-idiotype antibody* (as disclosed in Cheung et al.) does not sufficiently relate to administration of 1A7 antibody to *diseased* individuals, and that Cheung et al. should therefore not serve as a basis for obviousness (see page 14 of the response filed on May 29, 2001). However, this point is moot in view of removal of the Chatterjee patent as a reference.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a).

CONCLUSION

Applicants believe that all outstanding issues raised by the Office have been addressed and that the claims are now in condition for allowance, which is respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 304142000201. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: January 24, 2002

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